UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

February 21, 2013

MEMORANDUM

Subject: Efficacy Review for Valhalla, EPA File Symbol 4822-LOU; DB Barcode: D407575.

From: Ibrahim Laniyan, Ph.D.
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Applicant: SC Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403-2236

Formulation from the Label:

Active Ingredient	% by wt.
Alkyl dimethyl benzyl ammonium chloride	0.096 %
Octyl decyl dimethyl ammonium chloride	0.072 %
Dioctyl dimethyl ammonium chloride	0.036 %
Didecyl dimethyl ammonium chloride	0.036 %
Inert Ingredients:	99.760 %
Total	100.000 %

I. BACKGROUND

The product, Valhalla (EPA File Symbol 4822-LOU), is a new product. The applicant requested to register the product as a disinfectant (bactericide and virucide), a non-food contact sanitizer, and a mildew-fungistatic for use on hard, non-porous surfaces. The registrant submitted Certificate of Analysis for each one of the three lots used in efficacy studies. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package identified as D407575 contained a letter from the applicant's to EPA (dated December 7, 2012), three Certificates of Analysis, and the proposed label (dated 12/07/2012).

Note: The product Valhalla has alternative names of, "Valhalla 16908H94-F4A & Valhalla FB Int. TCR# 16908H98-F4".

II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: machinery, tools, tables, counters, floors, carts, shelves, made of plastic, glass, vinyl, porcelain and stainless steel. Directions on the proposed label provide the following information regarding use of the product:

> **To Disinfect**: Preclean heavily soiled areas. Spray 6-8 inches from hard non-porous surface(s) until thoroughly wet. Let stand for 5 minutes, then wipe.
>
> **To Sanitize**: Preclean heavily soiled areas. Spray 6-8 inches from hard non-porous surface(s) until thoroughly wet. Let stand for 30 seconds, then wipe.
>
> **To Control, Inhibit or Prevent Mold and Mildew**: Remove heavy soil prior to applying the product for treatment against mold and mildew. On hard non-porous surfaces, spray until thoroughly wet. Re-apply as needed.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers] To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Salmonella enterica* ATCC 10708 and

Staphylococcus aureus ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442.

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5×10^5 colony forming units per carrier. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Hard Surface Mildew Fungistatic Test: This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. BRIEF DESCRIPTION OF THE DATA

Note: The tested product lots 707D4, 707D6, and 707D8 (≥60 days old) were tested, respectively, at the following mean values concentrations of total quat: 0.214%, 0.215%, and 0.212%.

1. MRID 488813-09: "AOAC Germicidal Spray Method, Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442) *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538)", by Nicole Albert. Study conducted at ATS Labs. Study completion date – March 30, 2012. Project Number A12797.

This study was conducted against *Pseudomonas aeruginosa (*ATCC 15442), *Staphylococcus aureus* (ATCC 6538), and *Salmonella enterica* (ATCC 10708). Three lots (Lot Nos.707D4, 707D6, and 707D8 (≥60 days old)) of the product, Valhalla, were tested using ATS Labs protocol # JW01090911.GS.1 (copy provided). The product was received ready-to-use as an aerosol spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers per product lot per microorganism were inoculated with 10 µL of a 48-54 hour suspension of test organisms incubated at 35-37°C. The carriers were dried at 35-37°C for 38 minutes at 50% relative humidity (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and 30 minutes (*Salmonella enterica*) at 50% relative humidity. Each carrier in a horizontal position was sprayed at staggered intervals with the product at a distance of 4-6 inches from the carrier surface for 2 seconds. Each carrier remained in contact with the product for 5 minutes at 20-24°C and 13% relative humidity. Following exposure, the excess liquid was drained off the carrier. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.07% of Lecithin + 0.5% Tween 80 for neutralization and subculturing. All subcultures were incubated for 48±2 hours at 35-37°C, then stored at 2-8°C for 1 day. Following incubation and storage, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviation reported in the study was reviewed.

2. MRID 488813-10: "AOAC Germicidal Spray Method, Test Organism: *Enterobacter aerogenes (*ATCC 13048)" for GLP 707 Valhalla FB LCL 16908H140-1, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – April 27, 2012. Project Number A12927.

This study was conducted against *Enterobacter aerogenes (*ATCC 13048). Two lots (Lot Nos. 707D4 and 707D6) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.GS.7 (copy provided). The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µl of a 48-54 hour suspension of test organisms incubated at 25-30°C. The test culture was vortex mixed for 3-4 seconds and allowed to stand for ≥10 minutes prior to use. The carriers were dried at 51% relative humidity, for 30 minutes at 35-37°C. Each carrier in a horizontal position was sprayed at staggered intervals for 2 seconds with the product at a distance of 4-6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 21°C and 17% relative humidity. Following exposure, the excess liquid was drained off the carrier. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.07% of Lecithin + 0.5% Tween 80 for neutralization and subculturing. All subcultures were incubated for 48±2 hours at 25-30°C then visually examined

for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

3. MRID 488813-11: "AOAC Germicidal Spray Method, Test Organism: *Stretococcus pyogenes* (ATCC 19615) for GLP 707 Valhalla FB LCL 16908H140-1, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – April 23, 2012. Project Number A12935.

This study was conducted against *Streptococcus pyogenes* (ATCC 19615). Two lots (Lot Nos. 707D4 and 707D6) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.GS.3 (copy provided). The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µl of a 4 day suspension of test organisms incubated at 35-37°C. The carriers were dried at 66% relative humidity, for 30 minutes at 25-30°C. Each carrier in a horizontal position was sprayed at staggered intervals for 3 seconds with the product at a distance of 4-6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 21°C and 17% relative humidity. Following exposure, the excess liquid was drained off the carrier. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.07% of Lecithin + 0.5% Tween 80 for neutralization and subculturing. All subcultures were incubated for 48±2 hours at 35-37°C in 6% CO_2, then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviation reported in the study was reviewed.

4. MRID 488813-12: "AOAC Germicidal Spray Method, Test Organism: *Escherichia coli* O157:H7 (ATCC 35150)" for GLP 707 Valhalla FB LCL 16908H140-1, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – April 27, 2012. Project Number A12925.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Lot Nos. 707D4 and 707D6) of the product, , GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.GS.2 (copy provided). The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot inoculated with 10 µL of a 48-54 hour suspension of test organisms incubated at 35-37°C in CO_2. The carriers were dried at 50% relative humidity, for 30 minutes at 35-37°C. Each carrier in a horizontal position was sprayed at staggered intervals for 2-3 seconds with the product at a distance of 4-6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 21°C and 24% relative humidity. Following exposure, the excess liquid was drained off the carrier. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.07% of Lecithin + 0.5% Tween 80 for neutralization and subculturing. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

5. MRID 488813-13: "AOAC Germicidal Spray Method, Test Organism: *Listeria monocytogenes* (ATCC 19117)" for GLP 707 Valhalla FB LCL 16908H140-1, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – April 27, 2012. Project Number A12926.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lot Nos. 707D4 and 707D6) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.GS.6 (copy provided). The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot inoculated with 10 µL of a 48-54 hour suspension of test organisms incubated at 35-37°C in CO_2. The carriers were dried at 50% relative humidity, for 30 minutes at 35-37°C. Each carrier in a horizontal position was sprayed at staggered intervals for 2 seconds with the product at a distance of 4-6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 21°C and 17% relative humidity. Following exposure, the excess liquid was drained off the carrier. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.07% of Lecithin + 0.5% Tween 80 for neutralization and subculturing. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

6. MRID 488813-14: "AOAC Germicidal Spray Method, Test Organism: Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)" for GLP 707 Valhalla FB LCL 16908H140, by Anne Stemper. Study conducted at ATS Labs. Study completion date – April 10, 2012. Project Number A12928.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592). Two lots (Lot Nos. 707D4 and 707D6) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.GS.4 (copy provided). The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of a 48-54 hour suspension of test organisms incubated at 35-37°C in CO_2. The test culture was vortex mixed for 3-4 seconds and allowed to stand for ≥10 minutes prior to use. The carriers were dried at 16.5% relative humidity, for 30 minutes at 35-37°C. Each carrier in a horizontal position was sprayed at staggered intervals for 2 seconds with the product at a distance of 4-6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 23.9°C and 27.9% relative humidity. Following exposure, the excess liquid was drained off the carrier. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.07% of Lecithin + 0.5% Tween 80 for neutralization and subculturing. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) was verified on a representative culture by performing a Kirby Bauer Susceptibility assay. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 25923) as a control organism. An Oxacillin disc was placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) to Methicillin (Oxacillin).

7. MRID 488813-15: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organism: Virus – Herpes simplex virus type 1," for GLP 707 Valhalla FB LCL 16908H140, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – April 9, 2012. Project Number A12938.

This study was conducted against Herpes simplex virus type 1, Strain F(1) (ATCC VR-733), using RK (rabbit kidney) cells, obtained from ViroMed Laboratories, Inc., as the host system. Three lots (707D4, 707D6, and 707D8 (≥60 days old)) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.HSV1 (copy provided). The product was received ready-to-use as a trigger spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, separate dried virus films were sprayed for 2 seconds at a distance of 4-6 inches until the carrier surfaces were thoroughly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. Following exposure time, a 2.00 ml aliquot of neutralizer was added to each plate and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was split and passed through 2 Sephadex columns, and diluted serially by 10-fold. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.24 $\log_{10}$** for all three batches.

Note: Protocol deviation reported in the study was reviewed.

8. MRID 488813-16: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organism: Virus – Herpes simplex virus type 2," for GLP 707 Valhalla FB LCL 16908H140, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – April 9, 2012. Project Number A12939.

This study was conducted against Herpes simplex virus type 2, Strain G (ATCC VR-734), using RK (rabbit kidney) cells, obtained from ViroMed Laboratories, Inc., as the host system. Three lots (707D4, 707D6, and 707D8 (≥60 days old)) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.HSV2 (copy provided). The product was received ready-to-use as a trigger spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, separate dried virus films were sprayed for 2 seconds at a distance of 4-6 inches until the carrier surfaces were thoroughly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. Following exposure time, a 2.00 ml aliquot of neutralizer was added to each plate and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was split and passed through 2 Sephadex columns, and diluted serially by 10-fold. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.17 $\log_{10}$** for all three batches.

Note: Protocol deviation reported in the study was reviewed.

9. MRID 488813-17: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organism: Virus – Influenza A (H1N1) virus," for GLP 707 Valhalla FB LCL 16908H140, by Dawn Pierson. Study conducted at ATS Labs. Study completion date – April 12, 2012. Project Number A12943.

This study was conducted against Influenza A (H1N1) Virus, Strain A/PR/8/34 (ATCC VR-1469), using RMK (Rhesus monkey kidney) cells, obtained from ViroMed Laboratories, Inc., as the host system. Three lots (707D4, 707D6, and 707D8 (≥60 days old)) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.FLUA (copy provided). The product was received ready-to-use as a trigger spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of product, separate dried virus films were sprayed for 2 seconds at a distance of 4-6 inches until the carrier surfaces were thoroughly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. Following exposure time, a 2.00 ml aliquot of neutralizer was added to each plate and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was split and passed through 2 Sephadex columns, and diluted serially by 10-fold. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.00 $\log_{10}$** for all three batches.

Note: Protocol deviation reported in the study was reviewed.

10. MRID 488813-18: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organism: Virus – Respiratory Syncytial virus (RSV)," for GLP 707 Valhalla FB LCL 16908H140, by Shanen Conway. Study conducted at ATS Labs. Study completion date – May 17, 2012. Project Number A12931.

This study was conducted against Respiratory Synctial virus (RSV) Strain long (ATCC VR-26), using Hep-2 (human larynx carcinoma) cells, obtained from ViroMed Laboratories, Inc., as the host system. Three lots (707D4, 707D6, and 707D8 (≥60 days old)) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.RSV (copy provided). The product was received ready-to-use as a trigger spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, separate dried virus films were sprayed for 2 seconds at a distance of 4-6 inches until the carrier surfaces were thoroughly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. Following exposure time, a 2.00 ml aliquot of neutralizer was added to each plate and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was split and passed through 2 Sephadex columns, and diluted serially by 10-fold. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated

at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.06 log_{10}** for all three batches.

Note: Protocol deviation reported in the study was reviewed.

11. MRID 488813-19: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organism: Virus – Rotavirus," for GLP 707 Valhalla FB LCL 16908H140, by Shanen Conway. Study conducted at ATS Labs. Study completion date – March 30, 2012. Project Number A12932.

This study was conducted against Rotavirus Strain WA using MA-104 (Rhesus monkey kidney) cells, obtained from Diagnostic Hybrids, as the host system. Three lots (707D4, 707D6, and 707D8 (≥60 days old)) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911.ROT (copy provided). The product was received ready-to-use as a trigger spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of product, separate dried virus films were sprayed for 2 seconds at a distance of 4-6 inches until the carrier surfaces were thoroughly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. Following exposure time, a 2.00 ml aliquot of neutralizer was added to each plate and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was split and passed through 2 Sephadex columns, and diluted serially by 10-fold. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.20 log_{10}** for all three batches.

Note: Protocol deviation reported in the study was reviewed.

12. MRID 488813-20: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application), Test Organism: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352)" for GLP 707 Valhalla FB LCL 16908H140, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – April 18, 2012. Project Number A12934.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. 707D4, 707D6, and 707D8 (≥60 days old)) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911. NFS.1 (copy provided) against each of the target microorganisms for a contact time of 30 seconds at room temperature (21°C). The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. Five sterile glass carriers per product lot per organism were inoculated with 20µl of a 48-54 hour old suspension of the test organism. The inoculum was spread to within 1/8 inch of the edges of the carrier. The

carriers were dried at 35-37°C and a relative humidity of 40% for 20 minutes. Each carrier was sprayed for 3 seconds at a distance of 4-6 inches and was exposed to the use solution at 21°C for 30 seconds at 24% relative humidity. After exposure, treated carrier was transferred to 20 ml of neutralizer. Within 30 minutes, 1.0 ml and 0.1 ml aliquots of the 10^0 dilutions and 1.0 ml aliquots of 10^{-1} dilutions were plated in duplicate on Tryptic Soy Agar with 5% Sheep Blood. All plates were incubated for 48±4 hours at 35-37°C. Following incubation, and three days storage at 2-8°C, the subcultures were visually enumerated. Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and purity.

13. MRID 488813-21: "EPA Hard Surface Mildew-Fungistatic Test, Test Organism: *Aspergillus niger* (ATCC 6275)" for GLP 707 Valhalla FB LCL 16908H14-1, by Becky Lien. Study conducted at ATS Labs. Study completion date – April 20, 2012. Project Number A12924.

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (Lot Nos. 707D4 and 707D6) of the product, GLP 707 Valhalla, were tested using ATS Labs protocol # JW01090911. MSTAT (copy provided) against the target microorganism. The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. Ten one-by-one inch glazed ceramic tile carriers per product lot were inoculated with a suspension of the test organism. Each carrier was sprayed for 3 seconds at a distance of 4-6 inches, then allowed to drain. The carriers were placed inside petri dishes and dried at 35-37°C for 110 minutes with the lids ajar. All plates were incubated for 7 days at 25-30°C at 95% humidity. Following incubation, the subcultures were visually enumerated. Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and purity.

V. RESULTS

MRID Number	Organism	Contact Time	No. Exhibiting Growth/Total No. Tested			Average Dried Carrier Count (CFU/ carrier)
			Lot # 707D4	Lot # 707D6	Lot # 707D8	
488813-09	*Pseudomonas aeruinosa*	5 minutes	0/60	0/60	0/60	2.52×10^6
	Staphylococcus aureus		0/60	1/60	1/60	3.67×10^6
	Salmonella enterica		0/60	0/60	0/60	2.13×10^4
488813-10	*Enterobacter aerogenes*		0/10	0/10	-	1.53×10^7
488813-11	*Streptococcus pyogenes*		0/10	0/10	-	3.03×10^5
488813-12	*Escherichia coli* O157:H7		0/10	0/10	-	7.47×10^6
488813-13	*Listeria monocytogenes*		0/10	0/10	-	2.0×10^4
488813-14	Methicillin Resistant *Staphylococcus aureus* - MRSA		0/10	0/10	-	1.8×10^6

MRID Number	Organism	Description	Results			Dried Virus Control ($TCID_{50}$/0.1ml)
			Lot # 707D4	Lot # 707D6	Lot # 707D8	
488813-15	Herpes simplex virus type 1, Strain F(1) (ATCC VR-733)	$10^{-1.3}$ dilution	Cytotoxicity	Cytotoxicity	Cytotoxicity	$10^{6.04}$
		$10^{-2.3}$ to $10^{-8.3}$ dilutions	Complete Inactivation	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1mL	$\leq 10^{1.80}$	$\leq 10^{1.80}$	$\leq 10^{1.80}$	
		TCD_{50}/0.1mL	$10^{1.80}$	$10^{1.80}$	$10^{1.80}$	
		Log Reduction	≥4.24	≥4.24	≥4.24	
488813-16	Herpes simplex virus type 2, Strain G (ATCC VR-734)	$10^{-1.3}$ to $10^{-7.3}$ dilutions	Complete Inactivation	Complete Inactivation	Complete Inactivation	$10^{4.97}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.80}$	$\leq 10^{0.80}$	$\leq 10^{0.80}$	
		TCD_{50}/0.1mL	$\leq 10^{0.80}$	$\leq 10^{0.80}$	$\leq 10^{0.80}$	
		Log Reduction	≥4.17	≥4.17	≥4.17	
488813-17	Influenza A (H1N1) virus, Strain A/PR/8/34 (ATCC VR-1469)	$10^{-1.3}$ dilution	Cytotoxicity	Cytotoxicity	Cytotoxicity	$10^{5.80}$
		$10^{-2.3}$ to $10^{-7.3}$ dilutions	Complete Inactivation	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1mL	$\leq 10^{1.80}$	$\leq 10^{1.80}$	$\leq 10^{1.80}$	
		TCD_{50}/0.1mL	$10^{1.80}$	$10^{1.80}$	$10^{1.80}$	
		Log Reduction	≥4.00	≥4.00	≥4.00	
488813-18	Respiratory syncytial (RSV) virus, Strain long (ATCC VR-26)	$10^{-1.3}$ to $10^{-6.3}$ dilutions	Complete Inactivation	Complete Inactivation	Complete Inactivation	$10^{4.86}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.80}$	$\leq 10^{0.80}$	$\leq 10^{0.80}$	
		TCD_{50}/0.1mL	$\leq 10^{0.80}$	$\leq 10^{0.80}$	$\leq 10^{0.80}$	
		Log Reduction	≥4.06	≥4.06	≥4.06	
488813-19	Rotavirus, Strain WA	$10^{-1.3}$ dilution	Cytotoxicity	Cytotoxicity	Cytotoxicity	$10^{6.00}$
		$10^{-2.3}$ to $10^{-7.3}$ dilutions	Complete Inactivation	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1mL	$\leq 10^{1.80}$	$\leq 10^{1.80}$	$\leq 10^{1.80}$	
		TCD_{50}/0.1mL	$10^{1.80}$	$10^{1.80}$	$10^{1.80}$	
		Log Reduction	≥4.20	≥4.20	≥4.20	

MRID Number	Organism	Lot #	Geometric Mean # Survivors/Carrier (30 seconds)		Percent Reduction
			Post Treatment	Initial	
488813-20	*Staphylococcus aureus*	707D4	$<2.00 \times 10^1$	6.03×10^6	>99.9%
		707D6	$<2.00 \times 10^1$		>99.9%
		707D8	$<4.90 \times 10^1$		>99.9%
	Klebsiella pneumoniae	707D4	$<3.16 \times 10^1$	7.41×10^6	>99.9%
		707D6	$<3.63 \times 10^1$		>99.9%
		707D8	$<2.29 \times 10^1$		>99.9%

MRID Number	Organism	Carrier Number	Lot # 707D4 (Day 7 evaluation)		Lot # 707D6 (Day 7 evaluation)		Control (Day 7 visual evaluation)
			Visual	Magnified	Visual	Magnified	
488813-21	*Aspergillus niger (ATCC 6275)*	1	0%	0%	0%	0%	75%
		2	0%	0%	0%	0%	65%
		3	0%	0%	0%	0%	75%
		4	0%	0%	0%	0%	75%
		5	0%	0%	0%	0%	95%
		6	0%	0%	0%	0%	75%
		7	0%	0%	0%	0%	55%
		8	0%	0%	0%	0%	90%
		9	0%	0%	0%	0%	60%
		10	0%	0%	0%	0%	75%

VI. CONCLUSION

1. The submitted efficacy data **support** the use of the product, Valhalla (EPA File Symbol 4822-LOU), as a bactericide and virucide against the following microorganisms on hard, nonporous surfaces, when used undiluted, in the presence of a 5% organic soil load for a 5 minutes contact time.

Staphylococcus aureus	MRID # 488813-09
Salmonella enterica	MRID # 488813-09
Pseudomonas aeruginosa	MRID # 488813-09
Enterobacter aerogenes	MRID # 488813-10
Streptococcus pyogenes	MRID # 488813-11
Escherichia coli O157:H7	MRID # 487698-12
Listeria monocytogenes	MRID # 488813-13
Methicillin Resistant *Staphylococcus aureus* – MRSA	MRID # 488813-14
Herpes simples virus type 1	MRID # 488813-15
Herpes simples virus type 2	MRID # 488813-16
Influenza A (H1N1) virus, Strain A/PR/8/34	MRID # 488813-17
Respiratory Syncytial virus, Strain Long	MRID # 488813-18
Rotavirus	MRID # 488813-19

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data (MRID # 488813-20) **support** the use of the product, Valhalla (EPA File Symbol 4822-LOU), as a non-food contact surface sanitizer at room temperature, against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of a 5% organic soil load for a 30-second contact time.

3. The submitted efficacy data (MRID # 488813-21) **support** the use of the product, Valhalla (EPA File Symbol 4822-LOU), as a **7-day** hard surface mildew-fungicide at room temperature, against *Aspergillus niger* in the presence of a 5% organic soil load.

VI. LABEL

1. The proposed label claims are **acceptable** regarding the use of the product, Valhalla (EPA File Symbol 4822-LOU), as a disinfectant with bactericidal and virucidal activity for use on hard, non-porous surfaces against the following organisms when used undiluted in the presence of 5% organic soil, at room temperature, for a 5-minute contact time.

Staphylococcus aureus
Salmonella enterica
Pseudomonas aeruginosa
Enterobacter aerogenes
Streptococcus pyogenes
Escherichia coli O157:H7
Listeria monocytogenes
Methicillin Resistant *Staphylococcus aureus* – MRSA
Herpes simples virus type 1
Herpes simples virus type 2
Influenza A (H1N1) virus, Strain A/PR/8/34
Respiratory Syncytial virus, Strain Long
Rotavirus

They **are supported** by the applicant's data.

3. The proposed label claims are **acceptable** regarding the use of the product, Valhalla (EPA File Symbol 4822-LOU) as a hard, non-food surfaces sanitizer when used undiluted in the presence of 5% organic soil, at room temperature, for a contact time of 30 seconds. They **are supported** by the applicant's data.

4. The proposed label claims are **acceptable** regarding the use of undiluted Valhalla (EPA File Symbol 4822-LOU), as a mildew-fungistatic against *Aspergillus niger* (ATCC 6275). But registrant must specify **7-day** (one week) **inhibitory or growth prevention** claims as they **are supported** by the applicant's data.

For mold and mildew fungistatic claims, product must be allowed to dry onto surfaces. Registrant may use "Allow product to dry on the surface" before "Re-apply as needed".

5. The following revisions must be made to the proposed label:

- Page 7: Delete (Kills) (Eliminates) (Destroys) 99.9% of bacteria (on commonly) touched surfaces that can be transfer points for bacteria. This implies control of cross contamination.
- Page 8: Delete (kills) as optional language for sanitizing. Sanitization is a reduction in the number of organisms.
- Page 11: Revise "Helps prevent cross-contamination of (hard) (non-porous) surfaces" to read Helps prevent cross-contamination of treated hard non-porous surfaces.
- NOTE TO REVIEWER: Pages 6 & 7; has the PM Team allowed (> or ≥) 99.9% for killing germs, viruses and bacteria?